



DEC 19 2005

Thomas Hoxie
Novartis Pharmaceuticals Corp.
Patent and Trademark Dept.
564 Morris Ave.
Summit NJ 07901-1027

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,939,130

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,939,130, which claims the human drug product ZOMETA® (zoledronic acid), and a method of use of said product, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,755 days. U.S. Patent No. 4,939,130 has an original expiration date of November 13, 2007, subject to the provisions of 35 U.S.C. § 41(b). Accordingly, extension of the patent for 1,755 days will result in an extended expiration date of September 2, 2012.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 C.F.R. § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 1,755 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of February 28, 2003, with a correction notice published November 4, 2005. Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (2,292 \text{ days}) + 609 \text{ days} \\ &= 1,755 \text{ days}\end{aligned}$$

Since the regulatory review period began September 12, 1993, after the patent issue date (July 3, 1990), the entire period has been considered in the above determination. No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor the 14 year limitation of 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.	:	4,939,130
Granted	:	July 3, 1990
Original Expiration Date	:	November 13, 2007
Applicant	:	Knut A. Jaeggi, et al.
Owner of Record	:	Novartis Corporation

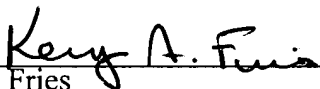
Title	:	Substituted Alkanediphosphonic Acids and Pharmaceceutical Use
Classification	:	514/94
Product Trade Name	:	ZOMETA® (zoledronic acid)
Term Extended	:	1,755 days
Expiration Date of Extension	:	September 2, 2012

Any correspondence with respect to this matter should be addressed as follows:

By mail: Commissioner for Patents
Box Patent Ext.
P.O. Box 1450
Alexandria, VA 22313-1450

By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to Mary C. Till at (571) 272-7755.


Kery Fries
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane
Rockville, MD 20857

Attention: Claudia Grillo

RE: ZOMETA® (zoledronic acid)
FDA Docket No.: 02E-0020